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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,988	05/06/2002	Masataka Nadaoka	2002-0074A	8710
513	7590	10/20/2006	EXAMINER	
WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			LUM, LEON YUN BON	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,988

Applicant(s)

NADAOKA ET AL.

Examiner

Leon Y. Lum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-12, 17-22, 25-31, and 36-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-12, 17-22, 25-31 and 36-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed August 2, 2006 is acknowledged and has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-3, 10-11, 17-22, 29-30, and 36-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakaya et al (EP 1 003 038 A1) in view of Wenz et al (US 3,715,192).

Nakaya et al teach an immunoassay device comprising a chromatography strip (i.e. development layer), labeling region 8 (i.e. marker reagent holding part), and a detection region 6 having an immobilized compound that specifically binds an analyte (i.e. reagent immobilization part). See page 3, sections 0013-0015 and 0020.

However, the teaching of Nakaya et al fail to disclose a space forming part which forms a cavity part, wherein said cavity part is a space into which the inspection target solutions flows by a capillary phenomenon, and wherein said space forming part is located only at a part upstream of said reagent immobilization part in a permeating direction of the inspection target solution.

Wenz et al teach a plastic film providing a hollow space above a capillary material, in order to ensure a defined and predetermined liquid volume to be absorbed, and also to prevent formation of undesired air bubbles between the capillary material and support backing. See column 2, lines 34-57.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include a hollow space via a plastic film, as taught by Wenz et al, above the

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chromatography strip of Nakaya et al, in order to ensure that a defined and predetermined liquid volume is absorbed, and also to prevent formation of undesired air bubbles between the strip and the substrate. The benefit of knowing a volume amount allows for quantitative results, thereby providing motivation to combine Nakaya et al and Wenz et al references. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in including the hollow space of Wenz et al in the apparatus of Nakaya et al, since Nakaya et al teach an exposed strip portion 5, and the hollow space of Wenz et al is applicable to exposed test strips.

In regards to claims 11 and 29, Wenz et al teach that at least one of the films is transparent. See column 3, lines 21-22.

In regards to claims 17 and 36, Wenz et al teach perforations in the cover film for additional ventilation. See column 3, lines 63-65.

In regards to claims 19 and 38, Wenz et al teach a dried nitrocellulose film on a substrate. See page 4, section 0035.

In regards to claims 42-43 and 45-46, Nakaya et al teach a protective laminate 3 that adheres to the chromatography strip and prevents exposure of the strip except for a portion 5. See page 2, section 008 and Figure 1.

6. Claims 6 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakaya et al (EP 1 003 038 A1) in view of Wenz et al (US 3,715,192) as applied to claims 1-2 above, and further in view of Bernstein et al (US 5,824,268).

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Nakaya et al and Wenz et al teachings have been disclosed above, but fail to teach that the mobile-reagent pad is a cell component destruction reagent part.

Bernstein et al reference teaches a membrane treated with a buffer containing 0.1 M ammonium chloride to lyse red blood cells, in order to deliver sample to the test strip that is essentially plasma with little contamination from whole red blood cells. See column 10, lines 49-54.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Nakaya et al and Wenz et al with a membrane treated with a buffer containing 0.1 M ammonium chloride to lyse red blood cells, as taught by Bernstein et al, in order to deliver sample to the test strip that is essentially plasma with little contamination from whole red blood cells. The advantage of purifying a test sample for easier assaying procedures provides the motivation for combining the teaching of Bernstein et al with the teachings of Nakaya et al and Wenz et al. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in including a membrane containing ammonium chloride to lyse red blood cells, as taught by Bernstein et al, in the device of Nakaya et al and Wenz et al, since Nakaya et al and Wenz et al teach chromatography strips, and the membrane of Bernstein et al is one type of chromatography strip.

7. Claims 7, 12, 26, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakaya et al (EP 1 003 038 A1) in view of Wenz et al (US 3,715,192) as applied to claims 1-2 above, and further in view of Killeen et al (US 5,166,051).

Nakaya et al and Wenz et al teachings have been disclosed above, but fail to teach a cell component shrinkage reagent part.

Killeen et al reference teaches a crenating agent in a membrane that functions to shrink RBC, in order to rigidify cells to make them less flexible so that they become trapped at the surface of a detection membrane and allow only the liquid analyte composition to flow through the membrane and penetrate the detection zone to provide to a viable signal. See column 5, lines 36-47.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Nakaya et al and Wenz et al with a crenating agent in a membrane that functions to shrink RBC, as taught by Killeen et al, in order to rigidify cells to make them less flexible so that they become trapped at the surface of a detection membrane and allow only the liquid analyte composition to flow through the membrane and penetrate the detection zone to provide to a viable signal. The crenating agent of Bernstein et al has the advantage of purifying a test sample for use in the device of Nakaya et al and Wenz et al, thereby providing motivation to combine the teaching of Bernstein et al with the teachings of Nakaya et al and Wenz et al. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in including a membrane containing a crenating agent to shrink cells, as taught by Killeen et al, in the device of Nakaya et al and Wenz et al, since Nakaya et al and Wenz et al teach chromatography strips, and the membrane of Killeen et al is one type of chromatography strip.

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8. Claims 8 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakaya et al (EP 1 003 038 A1) in view of Wenz et al (US 3,715,192) as applied to claims 1-2 above, and further in view of Barr (US 4,252,538).

Nakaya et al and Wenz et al teachings have been disclosed above, but fail to teach a bleaching reagent part.

Barr reference teaches distilled water that bleaches red blood cells, in order to cause rupture of the membrane and produce transparent red blood cells. See column 10, lines 14-35.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Nakaya et al and Wenz et al with distilled water that bleaches red blood cells, as taught by Barr, in order to cause rupture of the membrane and produce transparent red blood cells. The distilled water of Barr has the advantage of supplying clear red blood cells without optical contaminants in the device of Nakaya et al and Wenz et al, thereby providing motivation to include distilled water in the device of Nakaya et al and Wenz et al. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including distilled water, as taught by Barr, in the mobile-reagent pad of Nakaya et al and Wenz et al, since Nakaya et al and Wenz et al teach chromatography strips, and the membrane of Barr is one type of chromatography strip.

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9. Claims 9 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakaya et al (EP 1 003 038 A1) and Wenz et al (US 5,985,675) in view of Allen et al (US 5,416,000).

Allen et al reference teaches a sample receiving element that receives about 10 μ l volume of blood, in order to receive one or a series of small drops of blood. See column 5, lines 19-33.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Nakaya et al and Wenz et al with a sample receiving element that receives about 10 μ l volume of blood, as taught by Allen et al, in order to receive one or a series of small drops of blood. The advantage of performing an assay using just one or two drops prevents unnecessary drawing of blood, thereby providing motivation to combine the teaching of Allen et al with the teachings of Nakaya et al and Wenz et al. In addition, one of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a sample receiving element that receives about 10 μ l volume of blood, as taught by Allen et al, in the device of Nakaya et al and Wenz et al, since the test strip of Nakaya et al and Wenz et al is capable of measuring liquid samples, and blood drops of Allen et al are one type of liquid sample. Furthermore, the sample receiving element of Allen et al is also placed in a test strip. See column 7, line 41.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-3, 6-12, 17-22, 25-31, and 36-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/069,845 in view of Wenz et al (US 3,715,192).

The claims of the instant application recite a biosensor comprising a development layer for developing an inspection target solution as a specimen by making the inspection target solution permeate inwards, wherein said development layer includes a reagent immobilization part immobilized therein and a marker reagent holding part where a marker reagent which can be eluted by the development of the

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inspection target solution is held, wherein said biosensor measures a bonding amount of the marker reagent in said reagent immobilization part, thereby qualitatively or quantitatively measuring components to be measured in the inspection target solution, and wherein said biosensor further comprises a space forming part which forms a cavity part, wherein said cavity part is a space into which the inspection target solution flows by a capillary phenomenon, and a marker reagent holding part for holding a marker reagent which can be eluted by flowing-in of the inspection target solution, in said cavity part, wherein said space forming part is located only at a part upstream of said reagent immobilization part in a permeating direction of the inspection target solution, and wherein an amount of inspection target solution which flows into said cavity part is regulated by a volume of said cavity part.

Claims 1-25 of the copending application discloses a biosensor comprising a development layer wherein an inspection target solution is developed, and further comprising at least a marker reagent part where a marker reagent is held so as to be dissolved by the development of the inspection target solution in a part of the development layer, as well as a reagent immobilization part where a reagent which specifically reacts to an analysis target in the inspection target solution is immobilized in a part of the development layer. Claims 1-25 of the copending application also disclose directional permeation of the inspection target solution.

However, claims 1-25 of the copending application fails to teach a space forming part which forms a cavity part and wherein the space forming part is located only at a

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part upstream of said reagent immobilization part in a permeating direction of the inspection target solution.

Wenz et al teach a plastic film providing a hollow space above a capillary material, in order to ensure a defined and predetermined liquid volume to be absorbed, and also to prevent formation of undesired air bubbles between the capillary material and support backing. See column 2, lines 34-57.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include a hollow space via a plastic film, as taught by Wenz et al, above the development layer of the copending application, in order to ensure that a defined and predetermined liquid volume is absorbed, and also to prevent formation of undesired air bubbles between the strip and the substrate. The benefit of knowing a volume amount allows for quantitative results, thereby providing motivation to combine the copending application and Wenz et al references. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in including the hollow space of Wenz et al in the apparatus of the copending application, since the copending application teach an exposed strip portion, and the hollow space of Wenz et al is applicable to exposed test strips.

This is a provisional obviousness-type double patenting rejection.

12. The above provisional obviousness-type double patenting rejection is representative of double patenting rejections that are necessary between the instant application and a number of copending applications. The following list discloses the

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serial numbers of the other copending applications that would require similar provisional obviousness-type double patenting rejections as applied supra: 10,133,698 (claims 1 and 3-17); 10,398,711 (claims 1-19); 10,048,727 (claims 1-11); 10,242,672 (claims 14-17).

Response to Arguments

13. Applicant's arguments, see page 10 of the response (in the Remarks section), filed August 2, 2006, with respect to the rejection(s) of claim(s) 1-3, 6-12, 17-22, 25-31, and 36-46 under 35 U.S.C. 102(e) as being anticipated by Charm et al (US 5,985,675) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Nakaya et al (EP 1 003 038 A1) and Wenz et al (US 5,985,675).

Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leon Y. Lum
Patent Examiner
Art Unit 1641



LONG V. LE 6/16/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600